UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte ROBERT F. RIOUX, ROBERT GARABEDIAN,
and CHRISTOPHER PEARSON

Appeal 2007-2813
Application 10/685,744
Technology Center 3700

Decided: September 26, 2007

Before DEMETRA J. MILLS, ERIC GRIMES, and RICHARD M. LEBOVITZ, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an electrosurgical instrument. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

BACKGROUND

The Specification states that "[e]lectrosurgical instruments for delivering radio frequency (RF) electrical energy into solid tissue are known" (Specification 1). The Specification also states that, "[t]o enhance

heating and necrosis, saline may be injected into the target region before delivering electrical energy" and that this generally involves delivering saline from a syringe through a needle advanced into the tissue, and then energizing electrodes from an electrosurgical probe advanced into the target region to deliver RF energy (*id.* at 1-2).

> Because of inhomogeneities in the tissue of the target region, however, the saline injected by the syringe may not be perfused into the target region in a desired manner. For example, the saline may be perfused into tissue away from the electrodes, or only locally within a portion of the target region. Thus, the tissue within the target region may not be uniformly heated and necrosed as desired, possibl[y] requiring multiple treatments to ensure that the target region is successfully necrosed. In addition, where a separate syringe is used to deliver the saline, the syringe and probe require separate approaches into the tissue, complicating access and creating multiple tracks through the intervening tissue that may need to be closed and allowed to heal.

(*Id.* at 2.)

The Specification describes an apparatus "for delivering electrical energy to tissue within a patient, the apparatus including a tubular member having a proximal end, a distal end sized for insertion into a body of a patient and a lumen extending from the distal end towards the proximal end" (*id.* at 3). "One or more needles are extendable from the lumen beyond the distal end of the tubular member, each needle having a distal tip for penetrating tissue. At least one . . . of the one or more needles has an infusion lumen for delivering fluid to an outlet in its distal tip." (*Id.*) A "distal portion of the needle(s) may include a conductive region defining an electrode" (*id.*).

The Specification also discloses that "at least a distal portion of the needle(s) may be formed from a porous material, e.g., a sintered stainless steel" (*id.*). The Specification indicates that an "advantage of using a sintered/porous material to form the needle(s) is that visibility of the distal portion of the needle(s) under certain imaging modalities may be enhanced. For example, the sintered/porous material may substantially increase the echogenicity of the needle when using ultrasound imaging." (*Id.* at 28.) In addition, "[b]ecause of the porous nature of the sintered material, the saline may more uniformly permeate the surrounding tissue as compared with a needle including a lumen having only one or more discrete outlets" (*id.* at 28-29).

DISCUSSION

1. CLAIMS

Claims 1-16 are pending and on appeal. The claims subject to each rejection have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). We will focus on claim 1, which is representative and reads as follows:

> 1. An apparatus for delivering electrical energy to tissue within a patient, comprising:
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> a tubular member comprising a proximal end, a distal end having a size for insertion into a body of a patient, and a lumen extending from the distal end towards the proximal end; and
>
> a needle comprising a distal portion extending at least partially from the lumen and terminating in a tissue-piercing distal tip, the distal portion comprising an electrically conductive and porous material, thereby providing an electrode through which electrolytic fluid may flow for delivering electrical energy to tissue surrounding the distal portion.

2. PRIOR ART

The Examiner relies on the following references:

Rangaswamy	US 4,512,768	Apr. 23, 1985
Edwards	US 6,071,280	Jun. 6, 2000
VanTassel	US 6,241,710 B1	Jun. 5, 2001
Kirsch	US 6,503,225 B1	Jan. 7, 2003

3. OBVIOUSNESS

Claims 1-4 and 6-15 stand rejected under 35 U.S.C. § 103 as obvious over Edwards in view of VanTassel. The Examiner relies on Edwards for disclosing

> an apparatus for delivering electrical energy to tissue within a patient, comprising: a tubular member 12 comprising a proximal end 14, a distal end 16 having a size for insertion into a body of a patient, and a lumen extending from the distal end towards the proximal end (Fig. 2); and a needle 20 comprising a distal portion extending at least partially from the lumen and terminating in a tissue-piercing distal tip, the distal portion comprising an electrically conductive material, thereby providing an electrode through which electrolytic fluid may flow for delivering electrical energy to tissue surrounding the distal portion.

(Answer 4.) Referring to Figures 13-15, the Examiner finds that "Edwards clearly teaches delivering fluid through pores in at least one needle" (*id.* at 13).

The Examiner relies on VanTassel for teaching "a needle 2, wherein the distal portion comprises porous sintered stainless steel to allow fluid to flow through pores in the walls of the needle shaft" (*id.* at 4). The Examiner concludes that it would have been obvious "to have made the distal portion of the needle of Edwards et al. from porous sintered stainless steel in view of

the teaching of VanTassel et al. as an obvious alternate way of allowing fluid to flow through the walls of the needle shaft that is known in the art" (*id.*).

We agree with the Examiner that the references support a prima facie case of obviousness. Edwards describes "a tissue ablation apparatus that includes a delivery catheter, with distal and proximal ends" (Edwards, col. 3, ll. 51-54). "An electrode deployment apparatus is positioned at least partially in the delivery catheter. It includes a plurality of electrodes that are retractable in and out of the catheter's distal end." (*Id.* at col. 3, ll. 55-58.) "The electrodes can be hollow" (*id.* at col. 4, l. 23). "Sources of infusing mediums, including but not limited to electrolytic and chemotherapeutic solutions, can be associated with the hollow electrodes," which "can have sharpened, tapered ends in order to assist their introduction through tissue, and advancement to the selected tissue site" (*id.* at col. 4, ll. 35-39). As depicted in Figure 8, an electrode can "include a plurality of fluid distribution ports **26** . . . [to] permit the introduction and flow of a variety of fluidic mediums thorough [the] electrode . . . to the desired tissue site" (*id.* at col. 8, ll. 62-67).

VanTassel describes "a surgical needle with a weeping tip for microinjection of medicaments into a body surface" (VanTassel, col. 2, ll. 36-37). The needle comprises "a porous distal portion . . . adapted to cause a liquid injectate to weep or ooze therefrom multidirectionally under injection pressure while the distal portion and point of the needle are inserted into a body surface" (*id.* at col. 2, ll. 37-46). VanTassel discloses that the "distal portion of the needle can be fabricated from any of a number

of different 'open cell' porous materials," for example, porous sintered metal, such as from stainless steel (*id.* at col. 5, ll. 41-46). Alternatively, VanTassel describes creating a porous distal portion "from a non-porous material (e.g., metal) using a cutting laser and techniques known in the art to punch pores into the needle segment" (*id.* at col. 6, ll. 12-15).

We agree with the Examiner's reasoning that it would have been prima facie obvious to form Edwards' fluid distribution ports by either of the techniques described in VanTassel. Specifically, we agree that it would have been prima facie obvious to incorporate the fluid distribution ports by utilizing a porous material, such as sintered stainless steel.

Appellants argue that VanTassel is not analogous prior art because "VanTassel is neither in the field of the inventors' endeavor nor is it reasonably pertinent to the particular problem with which the inventors were concerned" (Br. 5).[1] Specifically, Appellants argue that

> the field of the inventors' endeavor is the ablative treatment of tumors . . . , whereas the field that VanTassel is concerned with is the injection of medicaments into tissue. . . . Furthermore, the particular problem with which the inventors were concerned with was making therapeutic ablations more efficient . . . , whereas the particular problem solved by VanTassel was providing a means for microinjecting controlled amounts of injectate to minimize leakage otherwise due to the rapid transfer of fluid.

(*Id.* at 5.)

We are not persuaded by this argument. "In order to rely on a reference as a basis for rejection of the applicant's invention, the reference

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[1] Our citations are to the "Supplemental Appeal Brief" filed September 5, 2006.

must either be in the field of the applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." *In re Oetiker*, 977 F.2d 1443, 1447 (Fed. Cir. 1992). We agree with the Examiner that Appellants have unduly limited at least the problem with which the inventors were concerned (Answer 12).

Claim 1 is directed to an apparatus for delivering electrical energy to tissue within a patient. The problem with which Appellants were concerned was how to also deliver fluid, specifically electrolytic fluid, to the tissue (Specification 1-2). In particular, as noted by Appellants, the Specification (page 2, lines 7-15) "recognizes that there is a problem [in] using a separate syringe to inject saline into the tissue to be ablated" (Reply Br. 3). To overcome this problem, the Specification describes including an infusion lumen for delivering fluid in one or more of the needles in the apparatus for delivering electrical energy (Specification 3). VanTassel relates to needles for delivering fluid to tissue within a patient (VanTassel, col. 2, ll. 35-49). Thus, we agree with the Examiner that VanTassel is reasonably pertinent to the particular problem with which the inventor was concerned.

Appellants also argue that "there is no suggestion in VanTassel to modify the Edwards ablation device in a manner that would render [claim 1] obvious" (Br. 6). In particular, Appellants argue that the "Examiner has not provided any reason why VanTassel would suggest, explicitly or implicitly, to one of ordinary skill in the art to make such a modification to the Edwards device" (*id.* at 7). Instead, "because the teachings of VanTassel are irrelevant to tissue ablation, they cannot be fairly applied to Edwards" (*id.*). "There is simply no suggestion from [VanTassel] that electrically conductive

fluid can be perfused from an RF ablation probe with porous needle electrodes to increase the size of the resulting ablation or provide any other advantage associated with RF ablation probes, such as increasing the echogenicity of the ablation probe" (*id.* at 8).

We are not persuaded by this argument. As pointed out by the Examiner, Edwards, which is directed to a tissue ablation apparatus, "teaches delivering fluid through pores in at least one needle" of the apparatus (Answer 13). Specifically, Edwards describes including fluid distribution ports (i.e., pores) in an electrode (i.e., a needle) of a tissue ablation apparatus to permit the introduction of fluidic mediums, such as electrolytic solutions, through the electrode to a desired tissue site (Edwards, col. 8, l. 62, to col. 9, l. 2).

The Examiner is merely relying on VanTassel to describe ways of including pores in the needle. Specifically, VanTassel describes fabricating the distal portion of the needle from porous sintered metal, such as sintered stainless steel (VanTassel, col. 5, ll. 41-46). It would have been obvious to those skilled in the art to form the pores in Edwards' apparatus by using porous sintered metal, such as sintered stainless steel, since VanTassel teaches that such material could be utilized in the form of a needle to deliver fluids to tissue, providing an obvious alternative to Edwards' hollow needles. "The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007). Appellants have not demonstrated that the alleged advantages of the combination are not predictable results.

We conclude that the Examiner has set forth a prima facie case that claim 1 would have been obvious over Edwards in view of VanTassel, which Appellants have not rebutted. We therefore affirm the rejection of claim 1 under 35 U.S.C. § 103. Claims 2-4 and 6-15 fall with claim 1.

Claim 5 stands rejected under 35 U.S.C. § 103 as obvious over Edwards in view of VanTassel and Rangaswamy, and claim 16 stands rejected under 35 U.S.C. § 103 as obvious over Edwards in view of VanTassel and Kirsch. The Examiner relies on Edwards and VanTassel as discussed above, and relies on Rangaswamy and Kirsch for the limitations of claims 5 and 16, respectively. (Answer 9-11.)

Appellants argue that Rangaswamy and Kirsch do not "supplement the failed teachings of Edwards and VanTassel" (Br. 9).

However, we have concluded that claims 1-4 and 6-15 are properly rejected under 35 U.S.C. § 103 over Edwards in view of VanTassel. Thus, we do not find Appellants' argument persuasive. We therefore affirm the rejections of claims 5 and 16 under 35 U.S.C. § 103.

SUMMARY

The Examiner's position is supported by the preponderance of the evidence of record. We therefore affirm the rejection of claims 1-16 under 35 U.S.C. § 103.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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